FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO. SERIAL NO.: (REV. 7.80) PATENT AND TRADEMARK OFFICE 120541-1013 09/488,364 LIST OF PRIOR ART CITED BY APPLICANT APPLICANT: (Use several sheets if necessary) Stephen J. Elledge, et al. FILING DATE: GROUP: January 12, 2000 1655 S. PATENT DOCUMENTS \*EXAMINER DOCUMENT NUMBER NAME CLASS SUBCLASS FILING DATE INITIAL (if appropriate) 5,302,706 04/12/94 Smith 23.1 11/02/92 OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) Hideo Toyoshima and Tony Hunter, "p27, A NOVEL INHIBITOR OF G1 CYCLIN-Cdk PROTEIN KINASE ACTIVITY, IS RELATED TO p21," Cell, Volume 78, July 15, 1994, pp. 67-74. Shou Waga, Gregory J. Hannon, David Beach & Bruce Stillman, "THE p21 INHIBITOR OF CYCLIN-DEPENDENT KINASES CONTROLS DNA REPLICATION BY INTERACTION WITH PCNA," Nature, Volume 369, June 16, 1994, pp. 574-578. Stephen J. Elledge and J. Wade Harper, "Cdk INHIBITORS: ON THE THRESHOLD OF CHECKPOINTS AND DEVELOPMENT," Cell Biology, 1994, pp. 847-850. Jin Jen, J. Wade Harper, Sandra H. Bigner, Darell D. Bigner, Nickolas Papadopoulos, Sanford Markowitz, James K.V. Willson, Kenneth W. Kinzler and Bert Vogelstein, "DELETION OF p16 and p15 GENES IN BRAIN TUMORS," Cancer Research, December 15, 1994, pp. 6353-6358. Gregory J. Hannon and David Beach, "p15 INXAB IS A POTENTIAL EFFECTOR OF TGF-B-INDUCED CELL CYCLE ARREST," Nature, Volume 371, September 15, 1994, pp. 257-261. Jamison Nourse, Eduardo Firpo, W. Michael Flanagan, Steve Coats, Kornella Polyak, Mong-Hong Lee, Joan Massague, Gerald R. Crabtree and James M. Roberts, "INTERLEUKIN-2-MEDIATED ELIMINATION OF THE p27Kip1 CYCLIN-DEPENDENT KINASE INHIBITOR PREVENTED BY RAPAMYCIN," Nature, Volume 372, December 8, 1994, pp. 570-573. Jun-Ya Kato, Masaaki Matsuoka, Kornelia Polyak, Joan Massague and Charles J. Sherr, "CYCLIN AMP-INDUCED G1 PHASE ARREST MEDIATED BY AN INHIBITOR (p27Kipl) OF CYCLIN-DEPENDENT KINASE 4 ACTIVATION," Cell, Volume 79, November 4, 1994, pp. 487-496. Hideo Toyoshima and Tony Hunter, "p27, A NOVEL INHIBOTOR OF G1 CYCLIN-CDK PROTEIN KINASE ACTIVITY, IS RELATED TO p21," Cell, Volume 78, July 15, 1994, pp. 67-74. Kornelia Polyak, Mong-Hong Lee, Hediye Erdument-Bromage, Andrew Koff, James M. Roberts, Paul Tempst and Joan

Bal

Richard A. Steinman, Barbara Hoffman, Augustine Iro, Christel Guillouf, Dan A. Lieberman and Motawa E. El-Houseini, "INDUCTION OF p21 (WAF-1/CIP1) DURING DIFFERENTIATION," Oncogene, 1994, pp. 3389-3396.

ANTIMITOGENIC SIGNALS," Cell, Volume 78, July 15, 1994, pp. 59-66.

Massague, "CLONING OF P27Kip1, A CYCLIN-DEPENDENT KINASE INHIBITOR AND A POTENTIAL MEDIATOR OF EXTRACELLULAR

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DATE CONSIDERED

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FORM PTO-1449  (REV. 7.80)  U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  LIST OF PRIOR ART CITED BY APPLICANT  (Use several sheets if necessary)		ATTY. DOCKET NO. 120541-1013	SERIAL NO.: 09/488,364		
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O MIN STEE		FILING DATE: January 12, 2000	GROUP: 1655		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)					
Hongpring Jiang, Jian Lin, DIFFERENTIATION IN HUMAN	Hongpring Jiang, Jian Lin, Zao-Zhong, Su, Frank R. Collart, Eliezer Huberman and Paul B. Fisher, "INDUCTION OF DIFFERENTIATION IN HUMAN PROMYELOCYTIC HL-60 LEUKEMIA CELLS ACTIVATES p21, WAF1/CIP1, EXPRESSION IN THE ABSENCE OF p53," Oncogene, 1994, pp. 3397-3406.  M. Saeed Sheikh, Xiao-Su Li, Jian-Chyi Chen, Zhi-Ming Shao, Jose V. Ordonex and Joseph A. Fontana, "MECHANISMS OF REGULATION OF WAF1/Cip1 GENE EXPRESSION IN HUMAN BREAST CARCINOMA: ROLE OF P53-DEPENDENT AND INDEPENDENT SIGNAL TRANSDUCTION PATHWAYS," Oncogene, 1994, pp. 3407-3415.  Paolo Michieli, Marcio Chedid, David Lin, Jacalyn H. Pierce, W. Edward Mercer and David Givol, "INDUCTION OF WAF1/CIP1 BY A P53-INDEPENDENT PATHWAY," Cancer Research, July 1, 1994, pp. 3391-3395.				
REGULATION OF WAF1/Cip1 G					
Jennifer A. Pierenpol, Ma Kastan, Kurt W. Kohn, Ste	Wafik S. El-Deiry, J. Wade Harper, Patrick M. O'Connor, Victor E. Velculescu, Christine E. Canman, Joany Jackman, Jennifer A. Pierenpol, Marilee Burrell, David E. Hill, Yisong Wang, Klas G. Wiman, W. Edward Mercer, Michael B. Kastan, Kurt W. Kohn, Stephen J. Elledge, Kenneth W. Kinzler and Bert Vogelstein, "WAF1/CIP1 IS INTRODUCED IN P53-MEDIATED G1 ARREST AND APOPTOSIS," Cancer Research, March 1, 1994, pp. 1169-1174.				
Harper and Stephen J. Ell	Susan B. Parker, Gregor Eichele, Pumin Zhang, Alan Rawls, Arthur T. Sands, Allan Bradley, Eric N. Olson, J. Wade Harper and Stephen J. Elledge, "P53-INDEPENDENT EXPRESSION OF p21 <sup>CIP1</sup> IN MUSCLE AND OTHER TERMINALLY DIFFERENTIATING CELLS," Science, Volume 267, February 17, 1995, pp. 1024-1027.				
Elledge and Steven I. Ree	Vjekoslav Dulic, William K. Kaufmann, Sandra J. Wilson, Thea D. Tisty, Emma Lees, J. Wade Harper, Stephen J. Elledge and Steven I. Reed, "P53-DEPENDENT INHIBITOR OF CYCLIN-DEPENDENT KINASE ACTIVITIES IN HUMAN FIBROBLASTS DURING RADIATION-INDUCED G1 ARREST," Cell, Volume 76, March 25, 1994, pp. 1013-1023.				
Dobrowolski, Chang Bai, L	isa Connell-Crowley, Eric	si, Brian Dynlacht, Li-Huei Tsai, Pumin Zhan Swindell, M. Pat Fox and Nan Wei, "INHIBITIO Cell, April 1995, Volume 6, pp. 387-400.			

Shou Waga, Gregory J. Hannon, David Beach and Bruce Stillman, "THE p21 INHIBITOR OF CYCLIN-DEPENDENT KINASES CONTROLS DNA REPLICATION BY INTERACTION WITH PCNA," Nature, Volume 369, June 16, 1994, pp. 574-578.

Hernan Flores-Rozas, Zvi Kelman, Frank B. Dean, Zhen-Qiang Pan, J. Wade Harper, Stephen J. Elledge, Michael O'Donnell and Jerard Hurwitz, "Cdk-INTERACTING PROTEIN 1 DIRECTLY BINDS WITH PROLIFERATING CELL NUCLEAR ANTIGEN AND INHIBITS DNA REPLICATION CATALYZED BY THE DNA POLYMERASE HOLOENZYME," Proc. Natl. Acad. Sci. USA, Volume 91, August 1994, pp. 8655-8659.

Stephen J. Elledge and J. Wade Harper, "Cdk INHIBITORS: ON THE THRESHOLD OF CHECKPOINTS AND DEVELOPMENT," Biology, 1994, pp. 847-852.

Manual Serrano, Gregory J. Hannon and David Beach, "A NEW REGULATORY MOTIF IN CELL-CYCLE CONTROL CAUSING SPECIFIC INHIBITION OF CYCLIN D/CDK4," Nature, Volume 366, December 16, 1993, pp. 704-707.

Asao Noda, Yi Ning, Susan F. Venable, Olivia M. Pereira-Smith and James R. Smith, "CLONING OF SENESCENT CELL-DERIVED INHIBITORS OF DNA SYNTHESIS USING AN EXPRESSION SCREEN," Experimental Cell Research 1994, pp. 90-98.

EXAMINER

B. J. Sisson

DATE CONSIDERED

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY, DOCKET NO. SERIAL NO.: (REV. 7.80) PATENT AND TRADEMARK OFFICE 120541-1013 09/488,364 LIST OF PRIOR ART CITED BY APPLICANT APPLICANT: (eral sheets if necessary) Stephen J. Elledge, et al. FILING DATE: GROUP: January 12, 2000 1655 OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) 818 Yue Xiong, Gregory J. Hannon, Hui Zhang, David Casso, Ryuji Kobayashi and David Beach, "p21 IS A UNIVERSAL INHIBITOR OF CYCLIN KINASES," Nature, Volume 366, December 16, 1993, pp. 701-704. Wafik S. El-Diery, Takashi Tokino, Victor E. Velculescu, Daniel B. Levy, Ramon Parsons, Jeffrey M. Trent, David Lin, W. Edward Mercer, Kenneth W. Kinzler and Bert Vogelstein, "WAF1, A POTENTIAL MEDIATOR OF p53 TUMOR SUPPRESSION," Cell, Volume 75, November 19, 1993, pp. 817-825. Mark J. Solomon, "ACTIVATION OF THE VARIOUS CYCLIN/cdc2 PROTEIN KINASES," Cell Biology, 1993, pp. 180-186. Charles J. Sherr, "G1 PHASE PROGRESSION: CYCLING ON CUE," Cell, Volume 79, November 18, 1994, pp. 551-555. Dawn Coverely, Mark Jackman and Julia Turner, "CYCLINS AND CYCLIN-DEPENDENT KINASES: TAKE YOUR PARTNERS," TIBS, June 1993, pp. 195-197. Tsutomu Nobori, Kaoru Miura, David J. Wu, Augusto Lois, Kenji Takabayashi and Dennis A. Carson, "DELETIONS OF THE CYCLIN-DEPENDENT KINASE-4 INHIBITOR GENE IN MULTIPLE HUMAN CANCERS," Nature, Volume 368, April 21, 1994, pp. 753-Kun-Liang Guan, Christopher W. Jenkins, Yan Li, Michael A. Nichols, Xiaoyu Wu, Christine L. O'Keefe, A. Gregory Matera and Yue Xiong, "GROWTH SUPPRESSION BY p18, a p16 INK4/MTS1 and p14 INK48/MTS2 - RELATED CDK6 IBHIBITOR, CORRELATES WITH WILD-TYPE pRb FUNCTION," Genes and Development, 1994, pp. 2939-2952. Jacob W. Udo, Elizabeth A. Lindsay, Richard A. Wells and Antonio Baldini, "MULTIPLE VARIANTS IN SUBTELOMERIC REGIONS OF NORMAL KARYOTYPES," Genomics, 1992, pp. 1019-1025. Olof H. Sudin, Heinz G. Busse, Melissa B. Rogers, Lorraine J. Gudas and Gregor Eichele, "REGION-SPECIFIC EXPRESSION IN EARLY CHICK AND MOUSE EMBRYOS OF GHOX-LAB AND HOX 1.6, VERTEBRATE HOMEOBOX-CONTAINING GENES RELATED TO DROSOPHILA LABIAL," Development, 1990, pp. 47-58. Beat Lutz, Shigeru Kuratani, Austin J. Cooney, Stefan Wawersik, Sophia Y. Tsai, Gregor Eichele and Ming-Jer Tsai, "DEVELOPMENTAL REGULATION OF THE ORPHAN RECEPTOR COUP-RFII GENE IN SPINAL MOTOR NEURONS," Development, 1994, pp. 25-36. Tim Durfee, Kathleen Becherer, Phang-Lang Chen, Shiou-Hwei Yeh, Yanzhu Yang, April E. Kilburn, Wen-Hwa Lee and Stephen J. Elledge, "THE RETINOBLASTOMA PROTEIN ASSOCIATES WITH THE PROTEIN PHOSPHATASE TYPE 1 CATALYTIC SUBUNIT" December 18, 1992, pp. 555-569. Charles H. Spruck III, Mirella Gonzalez-Zulueta, Atsuko Shibata, Anne R. Simoneau, Ming-Fong Lin, Felicidad Gonzales, Yvonne C. Tsai and Peter A. Jones, "p16 GENE IN UNCULTURED TUMOURS," Nature, Volume 370, July 21, 1994, pp. 183-184. Alexander Kamb, Qingyun Liu, Keith Harshman and Sean Tavtigian, "RATES OF p16 (MTS1) MUTATIONS IN PRIMARY TUMORS BJA WITH 9p LOSS," Science, Volume 165, July 15, 1994, pp. 415-417. DATE CONSIDERED 11-10-00

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO.: (REV. 7.80) PATENT AND TRADEMARK OFFICE 120541-1013 09/488,364 STOF PRIOR ART CITED BY APPLICANT APPLICANT: Several sheets if necessary) Stephen J. Elledge, et al. FILING DATE: GROUP: January 12, 2000 1655 OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.) 821 M.J. Pettenati, J.L. Haines, R.R. Higgins, R.S. Wappner, C.G. Palmer and D.D. Weaver, "WIEDEMANN-BECKWITH SYNDROME: PRESENTATION OF CLINICAL AND CYTOGENETIC DATA ON 22 NEW CASES AND REVIEW OF THE LITERATURE," Human Genetics, 1986, N.D. Hastie, "THE GENETICS OF WILMS' TUMOR - A CASE OF DISRUPTED DEVELOPMENT," Annu. Rev. Genet., 1994, pp. 523-558. B.R. Seizinger, H.P. Klinger, C. Junien, Y. Nakamura, M. Le Beau, W. Cavenee, B. Emanuel, B. Ponder, S. Naylor, F> Mitelman, D. Louis, A. Menon, I. Newsham, J. Decker, M. Kaelbling, I. Henry, A.v. Deimling, "REPORT OF THE COMMITTEE ON CHROMOSOME AND GENE LOSS IN HUMAN NEOPLASIA," Cytogenet Cell Genet, 1991, pp. 1080-1096. Ueli Gubler and Beth J. Hoffman, "A SIMPLE AND VERY EFFICIENT METHOD FOR GENERATING cDNA LIBRARIES," Elsevier Science Publishers, '983, pp. 263-269. F. L. Graham and A.J. Van Der Eb, "A NEW TECHNIQUE FOR THE ASSAY OF INFECTIVITY OF HUMAN ADENOVIRUS 5 DNA," Virology 52, 1973, pp. 456-467. Dan Y. Wu and R. Bruce Wallace, "THE LIGATION AMPLIFICATION REACTION (LAR) - AMPLIFICATION OF SPECIFIC DNA SEQUENCES USING SEQUENTIAL ROUNDS OF TEMPLATE-DEPENDENT LIGATION," Genomics, 1989, pp. 560-569. Stephen J. Elledge and J. Wade Harper, "Cdk INHIBITORS: ON THE THRESHOLD OF CHECKPOINTS AND DEVELOPMENT," Cell Biology, 1994, pp. 847-852. Mark G. Alexandrow and Harold L. Moses, "TRANSFORMING GROWTH FACTOR B AND CELL CYCLE REGULATION," Cancer Research, April 1, 1995, pp. 1452-1457. Kim Nasmyth and Tim Hunt, "DAMS AND SLUICES," Nature, Volume 366, December 16, 1993, pp. 634-635. Tony Hunter and Jonathon Pines, "CYCLINS AND CANCER 11: CYCLIN D AND CDK INHIBITORS COME OF AGE," Cell, Volume 79, November 18, 1994, pp. 573-582. Jesse Martinex, Ingo Georgoff, Joanne Martinez and Arnold J. Levine, "CELLULAR LOCALIZATION AND CELL CYCLE REGULATION BY A TEMPERATURE-SENSITIVE p53 PROTEIN," Genes and Development, 1991, pp. 151-159. Sander van den Heuvel and Ed Harlow, "DISTINCT ROLES FOR CYCLIN-DEPENDENT KINASES IN CELL CYCLE CONTROL," Science, Volume 262, December 24, 1993, pp. 2050-2054. Liang Zhu, Sander van den Heuvel, Kristian Helin, Ali Fattaey, Mark Ewen, David Livingston, Nicholas Dyson and Ed Harlow, "INHIBITION OF CELL PROLIFERATION BY p107, A RELATIVE OF THE RETINOBLASTOMA PROTEIN," Genes and Development, 1993, pp. 1111-1125. Stephen J. Elledge, Ronald Richman, Frederick L. Hall, Richard T. Williams, Naomi Lodgson and J. Wade Harper, "CDK2 814 ENCODES A 33-KDA CYCLIN A-ASSOCIATED PROTEIN KINASE AND IS EXPRESSED BEFORE CDC2 IN THE CELL CYCLE," Proc. Natl. Acad. Sci. USA, Volume 89, April 1992, pp. 2907-2911. EXAMINER R. J. Sinson DATE CONSIDERED 11-6-00

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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6	The state of the s	FILING DATE: January 12, 2000	GROUP: 1655		
MA	OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)				
BAR	Zhang, Gregory J. Hannon and David Beach, "p-21 CONTAINING CYCLIN KINASES EXIST IN BOTH ACTIVE AND INACTIVE STATES," Genes & Development, 1994, pp. 1750-1758.				
	Nat Sternberg, "BACTERIOPHAGE P1 CLONING SYSTEM FOR THE ISOLATION, AMPLIFICATION, AND RECOVERY OF DNA FRAGMENTS AS LARGE AS 100 KILOBASE PAIRS," Proc. Natl. Acad. Sci. USA, Volume 87, January 1990, pp. 103-107.				
	Matthew Meyerson and Ed Harlow, "IDENTIFICATION OF G1 KINASE ACTIVITY FOR cdk6, A NOVEL CYCLIN D PARTNER," Molecular and Cellular Biology, March 1994, Volume 14, No. 3, pp. 2077-2086.				
	Hitoshi Matsushime, Mark E. Ewen, David K. Strom, Jun-Ya Kato, Steven K. Hanks, Martine F. Roussel and Charles J. Sherr, "IDENTIFICATION AND PROPERTIES OF AN ATYPICAL CATALYTIC SUBUNIT (P34 <sup>psk-,3</sup> /CDK4) FOR MAMMALIAN D TYPE G1 CYCLINS," Cell, Volume 71, October 16, 1992, pp. 323-334.				
	Giulio Draetta, "CDC2 ACTIVATION: THE INTERPLAY OF CYCLIN BINDING AND THR161 PHOSPHORYLATION," Trends in Cell Biology, Volume 3, September 3, 1993, pp. 287-289.				
	Claudine Junien, "BECKWITH-WIEDEMANN SYNDROME, TUMOURIGENESIS AND IMPRINTING," Current Biology, 1992, pp. 431-438.				
	John Wiley & Sons, Inc., "CURRENT PROTOCOLS IN MOLECULAR BIOLOGY, VOLUME 1," 1994, Section III, 8 pages.				
	Orna Halevy, Bennett G. Novitch, Douglas B. Spicer, Stephen X. Skapek, James Rhee, Gregory J. Hannon, David Beach and Andrew B. Lassar, "CORRELATION OF TERMINAL CELL CYCLE ARREST OF SKELETAL MUSCLE WITH INDUCTION OF p21 BY MyoD," Science, Volume 267, February 17, 1995, pp. 1018-1021.				
BIL	L. Breeden and K. Nasmyth, "REGULATION OF THE YEAST HO GENE," pp. 643-650. (nolate)				
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EXAMINER DATE CONSIDERED 11/6/00		DATE CONSIDERED			
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